

SMG 1291.11

FDA STAFF MANUAL GUIDES, VOLUME I-ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF GENERIC DRUGS

OFFICE OF RESEARCH AND STANDARDS

DIVISION OF THERAPEUTIC PERFORMANCE

Effective Date: 01/24/2014

1. DIVISION OF THERAPEUTIC PERFORMANCE (DKKNUAA).

- A. Conducts regulatory science research to make generic versions of complex products available to the American public
- B. Conducts regulatory science research to establish equivalence standards for generic drugs that will ensure therapeutic equivalence
- C. Provides pre-submission scientific advice to ANDA sponsors on equivalence standards for generics drugs including complex products
- D. Ensures the therapeutic equivalence of approved generic drugs through post-approval research and investigation of potential safety, product use issues or bioequivalence problems

2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services and effective on January 24, 2014.